

## **REMARKS**

Claims 24-32 and 37-42 are pending in this application. Claims 1-23 and 33-36 have previously been cancelled without prejudice. Claim 30 has been amended herein. New claims 40-42 have been added. Support for the amendment and the newly added claims may be found throughout the specification and the figures, see for example, paragraphs 0001, 0029, 0033 and FIGS. 4 and 13. No new matter has been added.

Favorable consideration and allowance are respectfully requested.

### **I. Claim Rejections under 35 U.S.C. §103**

Claims 24-32 and 37-39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shaknovich (U.S. 5,669,924), Hilaire et al. (U.S. 2005/0085845) and Colgan et al. (U.S. 2003/0040789).

Applicants respectfully traverse the rejections based on the combinations of Shaknovich, Hilaire et al. and Colgan et al. Applicants respectfully request reconsideration of the rejected claims in light of the traversals and the claim amendment discussed below.

Applicants' claim 24 requires placing the first introducer and the second introducer in a staggered, adjacent configuration in a working channel of an endoscope and independently advancing the second introducer over the second wire guide from the working channel into the main lumen and the second branch lumen of the bifurcation entirely external to the first introducer. Claim 26 requires providing the first and second introducers disposed in a staggered, adjacent configuration in a working channel of an endoscope and advancing a second wire guide entirely external to and independent of the first stent. Claim 30 requires providing a first stent and a second stent in a staggered, adjacent, independently advanceable configuration in a working channel of an endoscope and distally advancing the second stent entirely external to the first stent and toward the second branch of the biliary system.

Shaknovich, Hilaire et al. and Colgan et al. have been discussed in detail in Applicants' previously filed responses. Briefly, Shaknovich is directed to stent assemblies for treating lesions in the bifurcating vessels in the coronary arteries. (Col. 3, line 60-Col. 6, line 68, describing special problems encountered when treating bifurcating coronary

vessels.) As acknowledged by the Examiner, Shaknovich fails to teach or suggest placing the first introducer and the second introducer in a staggered, adjacent configuration in a working channel of an endoscope. (Page 4, February 17, 2010, Office Action.)

Shaknovich also fails to teach or suggest advancing the first introducer from the working channel independent of the second introducer and advancing the second introducer from the working channel entirely external to the first introducer. In addition, Shaknovich fails to teach or suggest that the first stent is advanced toward the first branch of the biliary system and that the second stent is advanced toward the second branch of the biliary system as required by claim 30.

Hilaire et al. has been cited for disclosing placing and advancing introducers in a staggered relationship. Hilaire et al. is directed to catheter systems for performing angioplasty and vascular stenting. (Paragraph 0002.) The catheter systems of Hilaire et al. include a linking device that allows the catheters to be moved as a unit. (Abstract.) Hilaire et al. describes the advantage of the present invention over the "kissing balloons" technique in Shaknovich as follows: "An advantage of the present invention over prior methods is that the linking device 160 allows the catheter system 100 to be advanced as a unit and helps prevent premature or inadvertent dislodgement of the stent 150 from the catheters." (Paragraph 0073.) In other words, Hilaire et al. is teaching away from the method of Shaknovich and one skilled in the art would not be motivated to combine the method of Hilaire et al. having a linked system so that the first and second catheters 102, 104 are advanced together to deliver the stent 150 with Shaknovich using the "kissing balloon" system. Hilaire et al. also teaches away from advancing the second wire guide and second introducer independent of the first introducer as claimed in claim 24 or advancing a wire guide entirely external to and independent of the first stent as claimed in claim 26 or distally advancing the second stent entirely external to the first stent and toward the second branch of the biliary system as claimed in claim 30. In addition, as acknowledged by the Examiner, Hilaire et al. fails to teach or suggest that the first and second introducers are in a staggered, adjacent, configuration in a working channel of an endoscope. (Page 4, February 17, 2010, Office Action.)

Colgan et al. has been cited for disclosing the step of placing an introducer retaining a stent in a working channel of an endoscope. As previously discussed, Colgan et al. is directed to a **single** catheter having a **single** stent mounted at the distal end. Clearly, Colgan et al. also fails to teach or suggest first AND second introducers in a staggered, adjacent, configuration in a working channel of an endoscope.

Further, the Examiner's reason for combining Colgan et al. with Shaknovich and Hilaire et al. makes no sense. Shaknovich and Hilaire et al. are directed to vascular applications and there is no reason for providing an endoscope described in Colgan et al. for direct visualization of stent placement in the vasculature, both because of the size constraints in the vasculature and the ability of skilled artisans to place stents in the vasculature without direct visualization. One skilled in the art would not be motivated to combine Shaknovich or Hilaire et al with Colgan et al. for at least these reasons. In addition, one skilled in the art would not be motivated to combine Shaknovich with Hilaire et al. based on the teaching away of Hilaire et al. from the "kissing balloon" method described in Shaknovich. Although helpful insights need not become "rigid and mandatory formulas" such as the TSM test, the Supreme Court emphasized that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416, 418-19 (2007). The Supreme Court also cautioned that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." *Id.* at 421 (citing *Graham*, 383 U.S. at 36). Applicants respectfully assert that the rejection of claims 24, 26 and 30 based on the combination of Shaknovich, Hilaire et al. and Colgan et al. is relying on hindsight which is improper.

Even if Shaknovich, Hilaire et al. and Colgan et al. could be combined, none of these references teach or suggest placing the first introducer and the second introducer in a staggered, adjacent configuration in a working channel of an endoscope as required by claim 24, providing the first and second introducers disposed in a staggered, adjacent configuration in a working channel of an endoscope as required by claim 26 nor proving a

first stent and a second stent in a staggered, adjacent, independently advanceable configuration in a working channel of an endoscope as required by claim 30.

Thus, Applicants respectfully request the rejection of claims 24-32 and 37-39 under 35 U.S.C. §103(a) be withdrawn.

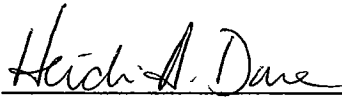
**II. Summary**

Having carefully addressed the Examiner's rejections, Applicants respectfully assert that the application is in condition for allowance. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

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